



UNITED STATES DEPARTMENT OF COMMERCE
Patent and Trademark Office

NOTICE OF ALLOWANCE AND ISSUE FEE DUE

HM32/0925

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APPLICATION NO.	FILING DATE	TOTAL CLAIMS	EXAMINER AND GROUP ART UNIT	DATE MAILED
09/251,274	02/16/99	063	CHAKRABARTI, A 1655	09/25/01
First Named Applicant	DI RIENZO,	35 USC 154(b) term ext. = 0 Days.		

TITLE OF INVENTION: METHODS FOR DETECTION OR PROMOTER POLYMORPHISM IN A UGT GENE PROMOTER

ATTY'S DOCKET NO.	CLASS-SUBCLASS	BATCH NO.	APPLN. TYPE	SMALL ENTITY	FEE DUE	DATE DUE
1	27373/35172	435-006.000	M51 UTILITY	YES	\$620.00	12/26/01

THE APPLICATION IDENTIFIED ABOVE HAS BEEN EXAMINED AND IS ALLOWED FOR ISSUANCE AS A PATENT. PROSECUTION ON THE MERITS IS CLOSED.

THE ISSUE FEE MUST BE PAID WITHIN THREE MONTHS FROM THE MAILING DATE OF THIS NOTICE OR THIS APPLICATION SHALL BE REGARDED AS ABANDONED. THIS STATUTORY PERIOD CANNOT BE EXTENDED.

HOW TO RESPOND TO THIS NOTICE:

I. Review the SMALL ENTITY status shown above.

If the SMALL ENTITY is shown as YES, verify your current SMALL ENTITY status:

- A. If the status is changed, pay twice the amount of the FEE DUE shown above and notify the Patent and Trademark Office of the change in status, or
- B. If the status is the same, pay the FEE DUE shown above.

If the SMALL ENTITY is shown as NO:

- A. Pay FEE DUE shown above, or
- B. File verified statement of Small Entity Status before, or with, payment of 1/2 the FEE DUE shown above.

II. Part B-Issue Fee Transmittal should be completed and returned to the Patent and Trademark Office (PTO) with your ISSUE FEE. Even if the ISSUE FEE has already been paid by charge to deposit account, Part B Issue Fee Transmittal should be completed and returned. If you are charging the ISSUE FEE to your deposit account, section "4b" of Part B-Issue Fee Transmittal should be completed and an extra copy of the form should be submitted.

III. All communications regarding this application must give application number and batch number. Please direct all communications prior to issuance to Box ISSUE FEE unless advised to the contrary.

IMPORTANT REMINDER: Utility patents issuing on applications filed on or after Dec. 12, 1980 may require payment of maintenance fees. It is patentee's responsibility to ensure timely payment of maintenance fees when due.

PATENT AND TRADEMARK OFFICE COPY

Notice of Allowability

Application No.

09/251,274

Applicant(s)

Di Rienzo et al.

Examiner

Arun Chakrabarti

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--The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance and Issue Fee Due or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9/12/01.
2. ☒ The allowed claim(s) is/are 1-6, 8-13, 15-21, 23-28, 30-62, 70, and 72-75.
3. ☒ The drawings filed on Feb 16, 1999 are acceptable as formal drawings.
4. ☐ Acknowledgement is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d).
- a) ☐ All b) ☐ Some* c) ☐ None of the:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).
- *Certified copies not received: _____.

5. ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application. **THIS THREE-MONTH PERIOD IS NOT EXTENDABLE FOR SUBMITTING NEW FORMAL DRAWINGS, OR A SUBSTITUTE OATH OR DECLARATION.** ~~This three-month period for complying with the REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL is extendable under 37 CFR 1.126(a).~~

6. ☐ Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient. A SUBSTITUTE OATH OR DECLARATION IS REQUIRED.
7. ☐ Applicant MUST submit NEW FORMAL DRAWINGS
- (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
- 1) ☐ hereto or 2) ☐ to Paper No. _____.
- (b) ☐ including changes required by the proposed drawing correction filed _____, which has been approved by the examiner.
- (c) ☐ including changes required by the attached Examiner's Amendment/Comment or in the Office action of Paper No. _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings. The drawings should be filed as a separate paper with a transmittal letter addressed to the Official Draftsperson.

8. ☐ Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Any reply to this letter should include, in the upper right hand corner, the APPLICATION NUMBER (SERIES CODE/SERIAL NUMBER). If applicant has received a Notice of Allowance and Issue Fee Due, the ISSUE BATCH NUMBER and DATE of the NOTICE OF ALLOWANCE should also be included.

Attachment(s)

- 1 ☐ Notice of References Cited (PTO-892)
- 2 ☐ Notice of Informal Patent Application (PTO-152)
- 3 ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 4 ☒ Interview Summary (PTO-413), Paper No. 20
- 5 ☒ Information Disclosure Statement(s) (PTO-1449), Paper No(s). 4 and 10
- 6 ☒ Examiner's Amendment/Comment
- 7 ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
- 8 ☒ Examiner's Statement of Reasons for Allowance
- 9 ☐ Other

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DETAILED ACTION

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CAR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with David Parker, on September 12, 2001.

The application has been amended as follows:

Claim 71 and non-elected claims 63-69 were canceled without prejudice towards further prosecution.

Claim 1 was amended by deleting the phrase----or eight-----.

Claim 1 was further amended by deleting the phrase -----and the presence of eight repeats correlates with decreased expression of the gene-----.

Claim 1 was further amended by deleting----, -----.

Claim 9 was amended by deleting the phrase----or eight-----.

Claim 9 was further amended by deleting the phrase -----and the presence of eight repeats correlates with decreased expression of the gene-----.

Claim 9 was further amended by deleting----, -----.

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Claim 16 was amended by deleting the phrase---or eight -----.

Claim 16 was further amended by deleting the phrase -----and the presence of eight repeats correlates with decreased expression of the gene-----.

Claim 16 was further amended by deleting----, -----.

Claim 24 was amended by deleting the phrase---or eight -----.

Claim 24 was further amended by deleting the phrase -----and the presence of eight repeats correlates with decreased expression of the gene-----.

Claim 24 was further amended by deleting----, -----.

Claim 33 was amended by deleting the phrase---and eight (TA) repeats [TA]8-----.

Claim 45 was amended by deleting the phrase---and eight (TA) repeats [TA]8-----

Claim 53 was amended by deleting the phrase---and eight (TA) repeats [TA]8-----

Claim 61 was amended by deleting the phrase---and eight (TA) repeats [TA]8-----

REASONS FOR ALLOWANCE

2. The present invention is directed to a method of detecting polymorphisms in a uridine diphosphate glucuronosyltransferase (UGT) gene promoter comprising determining the presence of five TA repeats in the promoter, wherein the presence of five TA repeats correlates with increased expression of the gene. Although, Beutler et al. (Proceedings of the National Academy of Sciences, USA, (July, 1998), Vol. 95, pages 8170-8174) teach a method of detecting polymorphisms in a uridine diphosphate glucuronosyltransferase (UGT) gene promoter

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comprising determining the presence of five TA repeats in the promoter, wherein the presence of five TA repeats correlates with increased expression of the gene, Beutler et al reference is not a prior art in view of the declaration under rule 131 in paper No: 14 submitted on June 5, 2001. In view of the absence of either teaching or suggestion of such a method of detecting polymorphisms in a uridine diphosphate glucuronosyltransferase (UGT) gene promoter comprising determining the presence of five TA repeats in the promoter, wherein the presence of five TA repeats correlates with increased expression of the gene, the present invention is novel and non-obvious.

Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

Conclusion

3. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Arun Chakrabarti, Ph.D., whose telephone number is (703) 306-5818. The examiner can normally be reached on 7:00 AM-4:30 PM from Monday to Friday. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Gary Jones, can be reached on (703) 308-1152. The fax phone number for this Group is (703) 305-7401. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number

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is (703) 308-0195.

Arun Chakrabarti,

Patent Examiner,

September 17, 2001



**JEFFREY FREDMAN
PRIMARY EXAMINER**